# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant: THOMAS W. DAVISON Confirmation No.: 7935

Serial No.: 10/689,487 Examiner: Nicholas W. Woodall

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Docket No.: 1291.1134103 Customer No.: 28075

Title: METHOD OF SECURING VERTEBRAE

### REPLY BRIEF

Mail Stop Appeal Brief - Patents Assistant Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

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Rachel Gagliardi

11-7-08

Pursuant to 37 C.F.R. § 41.41, Appellants hereby submit this Reply Brief in response to the Examiner's Answer mailed September 9, 2008.

In the Response to Argument section on page 5 of the Examiner's Answer, the Examiner asserts that the fusion devices 350 of Zdeblick are considered vertebra screws and the connector plate 365 with elongate arm 366 is considered the fastener. See FIG. 35. Appellants respectfully disagree. One of ordinary skill in the art would understand the fusion devices of Zdeblick as having a different structure and function, and would not consider fusion devices to be vertebra screws. Further, even if one did consider the fusion devices and connector plate of Zdeblick as the claimed screws and fastener, there is no motivation or reasonable expectation of success in attempting to place the fusion devices and connector plate of Zdeblick through the cannula of Foley et al., the viewing conduit of Ash et al., or some combination of the cannula and viewing conduit. Zdeblick specifically teach inserting a first fusion device through a laparoscope 170,

unseating the laparoscope from the first vertebra location and re-orienting it over the second location for placement of the second fusion device. See column 18, lines 5-14 and FIGS. 17-18. Zdeblick thus appears to teach inserting the one vertebral fusion device through a cannula or laparoscope and then moving the cannula to a second location for inserting the second fusion device. Zdeblick also teach using two endoscopes 142, 143 to visualize the working area. See column 12, lines 21-35 and FIG. 13.

Foley et al. appear to teach a similar method of performing a multi-level procedure involving multiple cannulas or moving the cannula:

multi-level procedures can be conducted by <u>sequentially inserting the</u> <u>working channel cannula</u> 20 through several small cutaneous incisions along the spinal mid-line. Alternatively, <u>several working channel cannulas</u> 20 can be placed at each of the small cutaneous incisions to perform the multi-level bone removal procedures.

Emphasis added; see column 13, line 64 through column 14, line 2. Both Foley et al. and Zdeblick thus appear to teach using a fixed diameter cannula for accessing a <u>single</u> working site for implantation of a screw or fusion device, and then <u>moving</u> the cannula or using multiple cannulas to insert a second screw or fusion device. Both Foley et al. and Zdeblick appear to teach the use of multiple cannulas to allow visualization of the working site using a <u>separate</u> viewing element. A combination of Foley et al. and Zdeblick thus appears to teach insertion of multiple screws or fusion devices <u>separately</u> through <u>fixed diameter devices</u> that are moved from first to second locations. Ash does not appear to provide any teaching or motivation for one of ordinary skill in the art to modify a combined device as taught by Foley et al. and Zdeblick to achieve the claimed system.

The Examiner asserts that Ash disclose improving the prior art devices by providing a device that allows for better viewing and operation room. Appellants submit that while Ash appears to provide a device for visualizing an operation site, Ash provides no motivation for one of ordinary skill in the art to modify Foley et al. and Zdeblick to achieve an elongate body sized and actuatable to permit passage of two fasteners and a fixation element and visualization of the two fasteners fixed to two adjacent vertebrae, as recited in the claims. Ash appear to teach a

device for the visual <u>inspection</u> of tissue within a patient, for performing medical procedures such as <u>biopsy</u> or <u>tissue sample collection</u>, and for <u>tissue ablation</u> by laser irradiation. There is no indication that the tissue sample collection device of Ash would function to allow passage of the implant and implant insertion devices of Foley and/or Zdeblick.

The Examiner states that Ash is not being used to teach passing implants and/or implant insertion device through the access device because Foley and Zdeblick clearly disclose these limitations, rather Ash is being used to teach a surgical instrument for performing surgical procedures having a distal end that expands to provide viewing and operation room. Appellants submit that in view of Foley et al.'s and Zdeblick's apparent teaching of either inserting a first implant or screw down a fixed diameter cannula to a first location, moving the cannula and inserting a second implant or screw to a second location, or using multiple cannulas at multiple locations to individually insert implants or screws, the addition of Ash would, at best, appear to provide motivation to expand the end of the visualization device to provide enhanced visualization of the single implant site. A combination of Foley et al., Zdeblick, and Ash still fails to teach a device actuatable to receive two fasteners and a fixation device and to permit visualization of the two fasteners fixed to two adjacent vertebrae, as recited in the claims.

The Examiner asserts that the claims do not require the passage to permit visualization of the two fasteners fixed to the vertebrae simultaneously. Appellants respectfully disagree. Claim 18, for example, recites in part, "the cross-sectional area of said passage at said first location is sized to permit visualization of two fasteners fixed to two adjacent vertebrae." The claim clearly states the passage permits visualization of two fasteners fixed to two adjacent vertebrae. Appellants submit that the common, ordinary meaning of the claim language is that the device permits visualization of A and B fixed to C and D, thus all four elements are viewed at the same time. Appellants submit that the use of the past tense, "fixed" indicates the two fasteners have already been fixed or attached to the two adjacent vertebrae. Thus, a passage that permits visualization of "two fasteners fixed to two adjacent vertebrae" would be understood by one of ordinary skill in the art as meaning the passage permits visualization of the two fasteners and the two adjacent vertebrae simultaneously. Appellants submit the Examiner's reliance on this

argument appears to be an acknowledgement that none of the references teaches or suggests a device with a passage sized to permit visualization of two fasteners fixed to two adjacent vertebrae.

The Examiner also argues that the references <u>could</u> provide visualization of two fasteners fixed to vertebrae if the assembly is used on the cervical area of the spine of a smaller organism. The Examiner has not provided any support for this conclusory statement.

The Examiner's argument on page 8 regarding the asserted teaching away by Foley et al. is not understood. The Examiner asserts that Foley's teaching of using a single cannula does not teach away from the modifications because no additional cannulas are being added by the teaching references. The argument presented in the Appeal Brief was actually one of Foley et al. apparently teaching the method asserted by the Examiner as being achieved by combining Foley et al., Zdeblick, and Ash. Because Foley et al. already teach insertion devices for visualizing implantation of their implants, and already achieve fixation or fusion of two adjacent vertebrae, there is no motivation for modifications by Ash. The teachings of Foley thus appear to teach away from such modifications by Ash. Foley already provides a system that provides direct viewing and operation room through a single working channel cannula. See column 4, lines 9-18. Foley thus actually appears to teach away from modifications to their system using Ash.

The Examiner again asserts that he believes the combination of Foley, Ash, and Zdeblick is capable of providing simultaneous viewing of two fasteners fixed to two adjacent vertebrae, but again has failed to provide any basis for such an assertion. It appears the Examiner has merely collected what are asserted as the elements of the claim without any reasoning as to why one of ordinary skill would be motivated to make the asserted combination. The Examiner has failed to provide the necessary articulated reasoning with any rational underpinning to support the conclusory statement of obviousness.

For the reasons stated above, the rejection of claims 18-23, 25-27, 30-36, 38-41 and 46-48 under 35 U.S.C. § 103(a), should be reversed.

Respectfully Submitted,

Dated: 11/7/08

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